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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/104,529 08/12/93 CLASSEN

18N2/1012

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WASHINGTON, DC 20004

| EXAMINER |
|----------|
| VOGEL, N |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 9 |

1805
DATE MAILED:

10/12/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/8/94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 2-18, 21-35 and 37 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 2-18, 21-35 and 37 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

08/104,524
AU 185

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-18, 21-35 and 37 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the specification which discloses a method of mammals which decreases the incidence of diabetes mellitus. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The rejection is repeated essentially for the reasons set forth in the previous office action, except that claims 17 and 21-35 are included in the present rejection due to applicants' amendment. Applicants have argued that the occurrence of any chronic immune mediated disorder would be expected to respond to the claimed immunization schedule the same as diabetes mellitus. However, this argument is not found to be convincing. In support of their argument, applicants cite several other patents. However, it is noted that each application is examined separately on its own merits. Applicants also cite a study of the occurrence of SLE in mice, which is summarized in the Declaration of Dr. Classen. However, it is not clear if the results stated by Dr. Classen are statistically significant; furthermore, this one study does not provide support commensurate with the scope of the claims, which recite any "chronic immune mediated disorder", or as in claim 15 "an autoimmune disease, asthma/allergy, and an immune mediated cancer". It is maintained that it has not been shown that undue experimentation would not be required to devise experimental procedures, including day of administration, type and amount of

immunogen, which would prevent the occurrence of the huge range of diseases, including cancer, encompassed by the claims. The application should not be an invitation to experimentation. The rejection is maintained.

Claims 2-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-18 are dependent on cancelled claim 1.

Claim 9 remains vague and indefinite in its recitation of "the method of claim wherein said...".

Claim 32 remains vague and indefinite in its recitation of "at least one pharmaceutically acceptable immunogen at least 11 days, but less than 26 days, after the last dose of said immunogen proceeding 26 days of age of said mammal". It remains unclear what is intended by this phrase.

Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

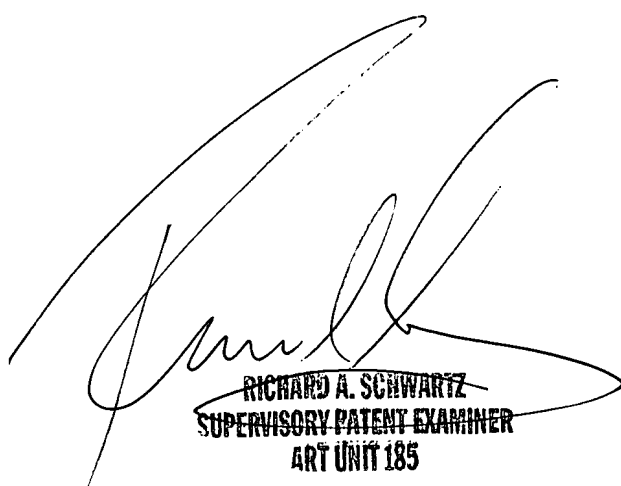
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1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel, whose telephone number is (703) 308-0278. The examiner can normally be reached on Monday through Wednesday from 7:00AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Schwartz, can be reached on (703) 308-1133. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 11, 1994



RICHARD A. SCHWARTZ
SUPERVISORY PATENT EXAMINER
ART UNIT 185